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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/848,909 | 05/04/2001 | R. John Collier | 00742/060002 | 7132 |

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| EXAMINER |
|---|
| PORTNER, VIRGINIA ALLEN |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1645 | 11 |

DATE MAILED: 07/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

| Application No. | Applicant(s) |
|---|---|
| 09/848,909 | Collier et al |
| **Examiner** | **Art Unit** |
| Portner | 1645 |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☒ Responsive to communication(s) filed on *May 4, 2001*.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under ***Ex parte Quayle***, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-28* are subject to restriction and/or election requirement.

**Application Papers**

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

## DETAILED ACTION

Claims 1-28 are pending.

I. Claims 1-5,6-8, 12-20, drawn to a plurality of mutated beta moieties of binary toxins, classified in class 530, subclass 350.

II. Claims 27-28, drawn to antibodies which bind to the naturally occurring B moiety, classified in class 530, subclass 387.1.

III. Claims 9-11 and 21-26, drawn to methods of preventing and treating infection with a mutated beta moiety of a binary toxin, classified in class 424, subclass 234.1.

1. The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using that product, wherein the toxin is useful in method of purifying antibodies, in methods of diagnosis of infection, and formualtion of molecular image polymers .

3. Inventions I and II are related as apparatus and product made. The inventions in this relationship are distinct if either or both of the following can be shown: (1) that the apparatus as claimed is not an obvious apparatus for making the product and the apparatus can be used for

making a different product or (2) that the product as claimed can be made by another and materially different apparatus (MPEP § 806.05(g)). In this case, that the product as claimed can be made by another and materially different apparatus, wherein the antibodies can be made recombinantly based upon the genetic material that encodes them, rather than through stimulation of an immune response to the toxin moiety .

4. Inventions II and III are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention Group II has separate utility such as a diagnostic reagent, a therapeutic reagent, an affintiy reagent used in methods of purifying toxin, and an immunogen in the production of anti-idiotypic antibodies. See MPEP § 806.05(d).

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

6. This application contains claims directed to the following patentably distinct species of the claimed invention:

Group I speices are as follows:

a. A plurality of Speices recited in claim 4 a)-r);

b. A plurality of Species shown in Table 1 presented by SEQ ID Nos 1-20;

c. A plurality of Species shown in Table 6;

d. Species defined through the deletion of amino acids 302-325 (D2L2-loop)

e. Speices that bind lethal factor

f. Species that bind edema factor

g.Species that bind to naturally occurring B moiety

h. Species that compete with naturally occuring B moiety for a surface receptor.

i. A plurality of toxins listed on page 4 , including (lines 7-15); and page 9, lines 5-22 with any of the specified mutations listed above;

j. A plurality of toxins with specified site mutations at page 8, lines 5-26; and page 19, lines 8-18.

Group II: Antibodies that bind to the native toxin with greater affintiy than to toxins with any one of the following mutations:

i. A plurality of Speices recited in claim 4 a)-r);

ii. A plurality of Species shown in Table 1 presented by SEQ ID Nos 1- 20;

iii. A plurality of Species shown in Table 6;

iv. Species defined through the deletion of amino acids 302-325 (D2L2-loop)

v. Speices that bind lethal factor

vi. Species that bind edema factor

vii.Species that bind to naturally occurring B moiety

viii. Species that compete with naturally occuring B moiety for a surface receptor.

ix. A plurality of toxins listed on page 4 , including (lines 7-15); and page 9, lines 5-22 with any of the specified mutations listed above;

x. A plurality of toxins with specified site mutations at page 8, lines 5-26; and page 19, lines 8-18.

Group III: Methods that administer one of the following beta moieties:

speices are as follows:

(1) Toxin Speices recited in claim 4 a)-r);

(2) Toxin species shown in Table 1 presented by SEQ ID Nos 1-20;

(3) Toxin Species shown in Table 6;

(4) Species defined through the deletion of amino acids 302-325 (D2L2-loop);

~~(5) Speices that bind lethal factor;~~

(6) Species that bind edema factor;

(7)Species that bnd to naturally occurring B moiety;

(8) Species that compete with naturally occuring B moiety for a surface receptor;

(9) toxins listed on page 4 , including (lines 7-15); and page 9, lines 5-22 with any of the specified mutations listed above;

(10) toxins listed with specified site mutations at page 8, lines 5-26; and page 19, lines 8-18.

7. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently,

Group I: Claims 1, 3, 6, 8 and 12 are generic.

Group II: Claims 27-28 are generic.

Group III: Claims 9-10, 21-22 are generic.

8. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

9. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations

of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

10. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

11. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242.

The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp
July 11, 2002

MARK NAVARRO
PRIMARY EXAMINER